

PSJ14 Janssen Opp Exh 63 – JAN-MS-05444730

From: Chikwendu, Valerie [SYNNA] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BF475540B4424EF5A4571A5BC00C8DC6-CCHIKWEN>
To: Dempsey, Michele [GPSUS]
Sent:
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Thanks, Michele!

From: Dempsey, Michele [GPSUS]
Sent: Friday, June 08, 2018 7:59 AM
To: Chikwendu, Valerie [SYNNA] <CCHIKWEN@ITS.JNJ.COM>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Made some tweaks below. Thank you!

From: Chikwendu, Valerie [SYNNA]
Sent: Friday, June 8, 2018 7:41 AM
To: Dempsey, Michele [GPSUS] <MDempse3@its.jnj.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Michele,
Here is the email I plan to send...

Thanks,
Valerie

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Hello Sudha,

Here are answers to your questions below. I have also cc'd Michele Dempsey, Director of Controlled Substances Compliance for further elaboration if needed.

DEA guidelines:

The DEA guidelines include an expectation for us to flag:

- Orders of unusual size
- Orders deviating substantially from normal pattern
- Orders of unusual frequency

We currently have a process to flag unusual based on list 1 chemicals and is not up to current Industry practice. The other two requirements are vulnerabilities that must be addressed. Our current monitoring program flags orders of unusual size (a running average of past orders is taken and we flag any order that is 300% more than average). We do not currently account for ordering frequency or cumulative effect of multiple orders in one month against a threshold and we plan to incorporate other ordering deviations based on patterns which will be defined as part of the project.

Other programs doing this within Commercial:

Not that we are aware of. The team is looking for other similar programs that we might be able to leverage from at the moment. One of our data management vendors has an order monitoring program

Capital/Expense Split

The estimates are for capital based on our assumptions that this will be a new development. Analytics team will define an approach which will further inform us on how we split it. We factored in the contingency amount of ~46K to cover expenses.

Please let me know if this helps to answer your question,

Regards,
Valerie

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From: Dzurenko, John [CONUS]
Sent: Thursday, June 07, 2018 1:34 PM
To: Chikwendu, Valerie [SYNNA] <CCHIKWEN@ITS.JNJ.COM>
Cc: Mani, Sudha [HCSUS] <SMani1@its.jnj.com>; Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Hi Val – Please address Sudha's 3 questions below. Thanks.

From: Mani, Sudha [HCSUS]
Sent: Thursday, June 7, 2018 1:32 PM
To: Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Agree that it is compliance related. Would like to understand

1. How this investment will meet the DEA requirement
2. Are there other programs that are doing this – ie within commercial
3. What is the cap/expense split

Thanks
Sudha

From: Dzurenko, John [CONUS]
Sent: Wednesday, June 06, 2018 1:23 PM
To: Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>; Mani, Sudha [HCSUS] <SMani1@its.jnj.com>
Cc: Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Thanks.. As far as I am concerned, this is an Absolute MUST DO compliance project and the increase should be incorporated into our LE numbers. Especially since we are trying to fill a \$3M Capital gap.

Sudha – Are you in agreement with this?

From: Purifoy, Katrina [HCSUS]
Sent: Wednesday, June 6, 2018 12:19 PM
To: Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>

Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Increasing from \$250K to \$900K.....

Katrina Purifoy

Process Capabilities and Strategy Director

J&J Health Care Systems Inc.

3955 E Holmes Rd Suite 401

Memphis, TN 38118

(901) 381-9624 (office #)

(479) 899-3101 (cell #)

From: Dzurenko, John [CONUS]

Sent: Wednesday, June 06, 2018 10:29 AM

To: Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>

Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Hi Katrina – Am I missing what the Capital Increase “ask” is? I don’t see it.

From: Purifoy, Katrina [HCSUS]

Sent: Wednesday, June 6, 2018 11:21 AM

To: Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>

Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Hello,

Will you be letting the group know if the additional 2018 funding is approved?

Katrina Purifoy

Process Capabilities and Strategy Director

J&J Health Care Systems Inc.

3955 E Holmes Rd Suite 401

Memphis, TN 38118

(901) 381-9624 (office #)

(479) 899-3101 (cell #)

From: Chikwendu, Valerie [SYNNA]

Sent: Monday, June 04, 2018 12:25 PM

To: Choy, Wai Yue [HCSUS] <wchoy@ITS.JNJ.com>; Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>;

Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>

Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Hello All,

The estimate for \$250,000 was made last year based on the following assumptions:

- Scope: The enhancement to our Controlled Substances Monitoring would include changes to our current algorithms on direct (SAP Atlas) orders.
- Solution: We would use an off-the-shelf solution (team identified one which was in the \$250k price range).

Here is what changed:

Additional information was gathered:

- DEA provided guidelines to manufacturers on what to include in Controlled Substances Monitoring programs – and fined another manufacturer \$35m for not monitoring/reporting suspicious orders for data other than direct order data (chargebacks).
- J&J hired a consultant last year to review our Controlled Substances Monitoring program. One of the gaps identified required additional data to be included in the Controlled Substances Monitoring system.
 - **Gap identified:** “*Current algorithm is based on List 1 chemicals guidance and not current Industry practice*”

- **Mitigation recommended:** "Increase SOM related data collection and analysis. Utilize IntegriChain data, data from Value Centric's Value Trak 852 and 867 EDI programs to evaluate and/or verify customer inventory levels and activities. Evaluate the usefulness of IMS data, particularly for planned future retail activities; Consider including ARCos historical purchase data to assist in establishing customer trends; Determine the feasibility of using State Prescription Drug Monitoring Program (PDMP) data (if available); Evaluate chargeback data and information in J&J's possession, and determine if any of the data or information is of value to the goals and objectives of the JOM SOM program."

Scope increase:

- Based on the new information, team expanded the scope of work to include analytics on wholesaler data and historical trends.
- As a result, two parallel solutions will be implemented. One to enhance current algorithms and a second one to consolidate wholesaler data and analyze trends for all applicable data.
- IT/Data analytics team recommended against using an off-the-shelf solution but instead build a solution which J&J would own and manage so that we can update as guidelines and regulations change.

Note: Figures are based on best estimates.

Do let me know if you have any other questions.

Thanks,
Valerie

From: Choy, Wai Yue [HCSUS]
Sent: Monday, June 04, 2018 12:07 PM
To: Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>; Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>
Cc: Chikwendu, Valerie [SYNNA] <CCHIKWEN@ITS.JNJ.COM>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Cc Valerie to help with more details.

From: Purifoy, Katrina [HCSUS]
Sent: Monday, June 04, 2018 12:06 PM
To: Dzurenko, John [CONUS] <JDzurenk@its.jnj.com>; Bruno, Rich [CPCUS] <rbruno@its.jnj.com>
Cc: Choy, Wai Yue [HCSUS] <wchoy@ITS.JNJ.com>
Subject: FW: Controlled Substances Project - Finding request (Follow Up)

Hi Gentlemen,
Please see the below capital JU/LE inquiry.....

Wai Yue,
I've reviewed the materials, but I'm not sure what exactly is causing the increase in the scope/capital requirement.
Please elaborate.

Thanks,
Katrina Purifoy
Process Capabilities and Strategy Director
J&J Health Care Systems Inc.
3955 E Holmes Rd Suite 401
Memphis, TN 38118
(901) 381-9624 (office #)
(479) 899-3101 (cell #)

From: Choy, Wai Yue [HCSUS]
Sent: Monday, June 04, 2018 7:44 AM
To: Purifoy, Katrina [HCSUS] <pkatrina@ITS.JNJ.com>
Cc: Mani, Sudha [HCSUS] <SMani1@its.jnj.com>; Maniscalco, Stephen [HCSUS] <smanisc@its.jnj.com>; Chikwendu, Valerie [SYNNA] <CCHIKWEN@ITS.JNJ.COM>
Subject: FW: Controlled Substances Project - Finding request (Follow Up)

Hi Katrina

This is for controlled substance order monitoring for Pharm:

84075	PROJECT	Controlled Substance_Order Monitoring	US
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The team had originally asked for \$250K based on preliminary scope and the ask is now \$0.9MM (\$0.7MM additional) due to an expanded scope.

As such, they will require a supplementary CAR.

I know there were some shifts in JU. From a budget perspective, do you have the latest LE to see if we can include this?

Thanks
WY

From: Chikwendu, Valerie [SYNNA]
Sent: Monday, June 04, 2018 5:54 AM
To: Choy, Wai Yue [HCSUS] <wchoy@ITS.JNJ.com>
Cc: Muhammad, Saad [CONCA] <smuhamm8@ITS.JNJ.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Sure. I've included the slide with high level milestones for Analytics and in addition, attached the kick-off slide deck.

From: Choy, Wai Yue [HCSUS]
Sent: Sunday, June 03, 2018 4:47 PM
To: Chikwendu, Valerie [SYNNA] <CCHIKWEN@ITS.JNJ.COM>
Cc: Muhammad, Saad [CONCA] <smuhamm8@ITS.JNJ.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Hi Valerie

Can you provide the PPT?

Thanks

From: Chikwendu, Valerie [SYNNA]
Sent: Friday, June 01, 2018 4:56 PM
To: Choy, Wai Yue [HCSUS] <wchoy@ITS.JNJ.com>
Subject: RE: Controlled Substances Project - Finding request (Follow Up)

Hi Wai Yue,

Checking in to see if you have had the chance to identify a finance representative for the Controlled Substances. Also checking to see if any progress on the funding request.

Thanks,

Valerie

From: Chikwendu, Valerie [SYNNA]
Sent: Thursday, May 31, 2018 6:26 PM
To: Choy, Wai Yue [HCSUS] <wchoy@its.jnj.com>
Subject: Controlled Substances Project - Finding request (Follow Up)
Importance: High

Hi Wai Yue,

Thanks for agreeing to follow up on the funding request for the CSM project. I was able to get the additional estimates. (See below). These estimates are based on what we know today and subject to change.

As discussed, I am asking for:

1. A CLS finance representative to support the project
2. Additional funding to cover increased scope of work – driven by new DEA guidelines (\$717,776.92)

Thanks for accommodating my *rushed* request to secure approval by our target date of tomorrow – Friday, June 1. I will follow up with you then to get your feedback. In the meantime, let me know if there is any additional information you might need.

Have a great evening!

Valerie

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Technical Services hourly rate	\$ 150.00
Analysis Group hourly rate	\$ 390.00
Total	\$ 921,692.31
Already in budget	\$ 250,000.00
Forecasted spend (addn'nl)*	\$ 671,692.31
Contingency (5%)	\$ 46,084.62
Need	<u>\$ 717,776.92</u>

Vendor/Provider/Task
Direct Orders and Wholesaler Orders
Direct Orders and Wholesaler Orders
Direct Orders
Wholesaler Orders
Direct Orders
Wholesaler Orders
Direct Orders
Wholesaler Orders

Other - (Purchase 867 and other)
Vendor/Provider
Integrichain or ValueChain
Contingency (5%)
5% Contingency

*Reason for additional spend: DEA guidelines specify that manufactures should have oversight over not only their direct orders but also orders received by their suppliers. Based on this guideline, project implementation will include Wholesaler orders.

For your reference, here is some background information on the project:

Project Definition:

Project will enhance current suspicious order monitoring program to ensure that we are actively stopping and reporting suspicious orders of scheduled controlled substances.

Challenge faced:

As a result of the Opioid crises, there has been tightened regulation from DEA including lawsuits and a recent \$35m fine imposed on another manufacturer for not identifying and reporting a suspicious order. New state laws and DEA guidelines are not covered in our current order monitoring program and procedures.

Project will deliver:

- An enhanced Suspicious Ordering Program which complies with applicable state and DEA regulations.
Solution will include:
 - Procedures that document the program and supporting processes
 - Order Monitoring Algorithm
 - Data Analytics
 - Monthly Compliance reviews
 - Investigations/Documentation for order release
 - Training
 - Customer due diligence (visits, questionnaires)

- Product monitoring (google alerts)
- State legislation monitoring and response to regulation changes
- State/Federal level government engagement/collaboration (DEA, FDA, State PDMP, NASCSA, etc)

- Enhanced system will include:

- Ability for systems to analyze data, identify patterns and flag suspicious orders
- Greater intelligence on direct orders and wholesaler orders of schedule products

Valerie

Valerie Chiamaka Chikwendu

Project Manager

CLS Strategy and Capability PMO

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